

16C1 5/79 GPM 1643
#517R
04/27/99

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Zemlan et al.

Serial No.: 09/035,708

Filed: March 5, 1998



Docket No.: 1259-0064

Examiner: Wilkens, K.

Art Unit: 1643

MAR 12 1999

GROUP 1800

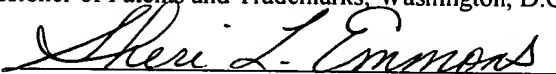
Title: METHOD OF DETECTING AXONAL DAMAGE, ASSOCIATED DISEASE STATES, AND RELATED MONOCLONAL ANTIBODIES AND PROTEIN CONTROLS THEREFOR

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(A)

Date of Deposit: March 3, 1999

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage by first-class mail in an envelope addressed to Commissioner of Patents and Trademarks, Washington, D.C. 20231.


Sheri L. Emmons

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

As authorized and encouraged under 37 C.F.R. §§ 1.97-1.98 and the provisions of MPEP §§609 and 707.05(b), Applicants submit herewith certain supplemental patent references, publications and/or other information which the Patent and Trademark Office may wish to consider in examining the above identified patent application.

The identification of any document herein is not intended to be, and should not be understood as being, an admission that each document, in fact, constitutes "prior art" within the meaning of the applicable law. The references are listed below and on attached form PTO-1449.

U.S. PATENT DOCUMENTS

| U.S. Patent No. | Inventor(s) |
|-----------------|--------------------|
| 5,733,734 | Trojanowski et al. |

FOREIGN PATENT DOCUMENTS

| Country | Patent No. | Inventor(s) |
|---------|------------|-------------|
| None | | |

copy

OTHER DOCUMENTS

1. Rosengren et al., Patients with Amyotrophic Lateral Sclerosis and Other Neurodegenerative Diseases Have Increased Levels of Neurofilament Protein in CSF, *J. of Neurochemistry* 67(5):2013-2018 (1996).
2. Adams et al., Diffuse Axonal Injury in Head Injury: Definition, Diagnosis and Grading, *Histopathology* 15:49-59 (1989).
3. Gotow and J. Tanaka, Phosphorylation of Neurofilament H. Subunit as Related to Arrangement of Neurofilaments, *J. Neuroscience Res.*, 37:691-713 (1994).
4. Binder et al., The Distribution of Tau in the Mammalian Central Nervous System, *J Cell Biology*, 101:1371-1378 (1985).
5. Greenberg et al., Hydrofluoric Acid-treated τ PHF Proteins Display the Same Biochemical Properties as Normal τ , *J. of Biochemical Chem.*, 267(1):564-569 (1992).
6. Kosik and E. Finch, MAP2 and Tau Segregate into Dendritic and Axonal Domains After the Elaboration of Morphologically Distinct Neurites: An Immunocytochemical Study of Cultured Rat Cerebrum, *J. Neuroscience*, 7(10):3142-3153 (1987).
7. Kosik et al., Developmentally Regulated Expression of Specific Tau Sequences, *Neuron* 2:1389-1397 (1989).

8. Litman et al., Subcellular Localization of Tau mRNA in Differentiating Neuronal Cell Culture: Implications for Neuronal Polarity, *Neuron* 10:627-638 (1993).
9. Wolozin et al., A Neuronal Antigen in the Brains of Alzheimer Patients, *Science*, 232:648-650.
10. Caputo et al., Immunological Characterization of the Region of Tau Protein That is Bound to Alzheimer Paired Helical Filaments, *Neurobiology of Aging*, 13:267-274 (1992).
11. Endoh et al., Lack of Carboxyl Terminal Sequence of Tau in Ghost Tangles of Alzheimer's Disease, *Brain Res.*, 601:164-170 (1993).
12. Carmel et al., The Structural Basis of Monoclonal Antibody Alz50's Selectivity for Alzheimer's Disease Pathology, *J. Biological Chem.*, 271(51):32789-32795 (1996).
13. Otvos et al., Monoclonal Antibody PHF-1 Recognizes Tau Protein Phosphorylated at Serine Residues 396 and 404, *J. of Neuroscience Res.*, 39:669-673 (1994).
14. Zemlan and G. Dean, Monoclonal Antibody PHF-9 Recognizes Phosphorylated Serine 404 of Tau Protein and Lables Paired Helical Filaments, *J. Neuroscience Res.*, 46:90-97.
15. Lee and S. Rook, Exprssion of Tau Protein in Non-neuronal Cells: Microbulule Binding and Stabilization, *J. of Cell Sci.*, 102:227-237(1992).
16. Anderton et al., Monoclonal Antibodies Show That Neurofibrillary Tangles and Neurofilaments Share Antigenic Determinants, *Nature* 298:84-86 (1982).
17. Goedert et al., Multiple Isoforms of Human Microtubule-Associated Protein Tau: Sequences and Localization in Neurofibrillary Tangles of Alzheimer's Disease, *Neuron*, 3:519-526 (1989).
18. Arai et al., Cerebrospinal Fluid Tau Levels in Neurodegenerative Diseases with Distinct Tau-Related Pathology, *Biochem, and Biophysical Res. Comm.*, 236:262-264 (1997).
19. Mori et al., Tau in Ceberospinal Fluids: Establishment of the Sandwich ELISA with Antibody Specific to the Repeat Sequence in Tau, *Neurosci. Letters*, 186:181-183 (1995).
20. Johnson et al., The τ Protein in Human Cerebrospinal Fluid in Alzheimer's Disease Consists of Proteolytically Derived Fragments, *J. NeuroChemistry*, 68(1):430-433 (1997).
21. Munroe et al., Tau Protein in Ceberospinal Fluid as an Aid in Diagnosis of Alzheimer's Disease, *Annals of Clinical and Lab. Sci.*, 25(3):207-217.

22. Vigo-Pelfrey et al., Elevation of Microtubule-associated Protein Tau in the Cerebrospinal Fluid of Patients With Alzheimer's Disease, *Neurology*, 45:788-793 (1995).
23. Lycke et al., Neurofilament Protein in Cerebrospinal Fluid: A Potential Marker of Activity in Multiple Sclerosis, *Short Report* (1997).
24. Tullberg et al., CSF Neurofilament and Glial Fibrillary Acidic Protein in Normal Pressure Hydrocephalus, *Neurology*, 50:1122-1127.
25. Greenberg et al., Hydrofluoric Acid-treated τ_{PHF} Proteins Display the Same Biochemical Properties as Normal τ^* , *J. Biological Chem.*, 267(1):564-569.

A copy of each document is included for the express purpose of providing the Patent and Trademark Office with ample opportunity to evaluate the same and arrive at an independent assessment of the materiality of each, if any, to the examination of the above-identified application.

In reviewing the enclosed copies of the above documents, the Examiner is instructed to ignore any underscoring or highlighting which may have been done because such markings may or may not have any relationship to the subject matter of the above-identified application. The copies being submitted with this "Information Disclosure Statement" are the best copies available at this time.

The identification of any document herein is not intended to be, and should not be understood as being, an admission that each such document, in fact, constitutes "prior art" within the meaning of applicable law.

Applicant respectfully requests that the documents cited herein be made of record in the normal manner and that such documents appear on the printed patent as being considered and made of record.

Respectfully submitted,

Date: March 3, 1999

By: _____

Roger A. Gilcrest

Registration No.: 31,954

— Standley & Gilcrest

495 Metro Place South, Suite 210

Dublin, Ohio 43017-5315

Telephone: (614) 792-5555

Facsimile: (614) 792-5536